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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,703	02/20/2002	Craig Anderson	1/1282	7672

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/079,703

Applicant(s)
Anderson et al.

Examiner
Phyllis G. Spivack

Art Unit
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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An Information Disclosure Statement filed November 13, 2003, Paper No. 4, is acknowledged and has been reviewed.

Claims 1-10 are under consideration.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 9 and 10 provide for the use of an ANG II antagonist and telmisartan, respectively, but, since the claims do not set forth any steps involved in the method/process, it is unclear what methods Applicants are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9 and 10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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Claim 8 is rejected under 35 U.S.C. 102(a) as being anticipated by Weber, M.A., American Journal of Cardiology.

Weber teaches the pharmaceutical combination of telmisartan in an amount of 80 mg and ramipril, an ACE inhibitor in an amount of 10 mg. Intended use confers no patentable weight to composition claims. *In re Hack* 114 USPQ 161.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mihm et al., U.S. Patent 5,565,469.

Mihm teaches angiotensin II antagonists that are benzimidazoles, preferably in the range of 1-70 mg, in combination with ACE inhibitors for use in the treatment of disorders of cognitive functions. See formula I where R₁ may be methyl, R₂ may be 1-methylbenzimidazol-2-yl, R₃ may be n-propyl and R₄ may be formyl, resulting in the sartan compound telmisartan. See column 15, lines 5-34. The recited dose of the ACE inhibitor is described as 1/5 to 1/1 of the lowest normal dose of the angiotensin II inhibitor. The claims differ in that there are no examples disclosed wherein dosage ranges in mg/kg amounts are taught. However, in view of Mihm's teaching, one skilled in the art would have been motivated to prepare a pharmaceutical composition comprising an ANG II antagonist and an ACE inhibitor to treat disorders of

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cognitive function. Such would have been obvious in the absence of evidence to the contrary because combination therapy of an angiotensin II antagonist with an ACE inhibitor, including those recited in instant claim 2, are known in the prior art. Mihm specifically includes disorders of cognitive function as pathologies to which the combination therapy is directed. The determination of both optimal dosages of both active ingredients and optimal modes of administration are parameters well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

Tamura, M., U.S. 2003/0083339, is cited to show further the state of the art with respect to combinations of ANG II antagonists and ACE inhibitors. See claims 28, 35 and 36. Further, see page 11, paragraph [0126] where antagonists of angiotensin II are useful in treating cognitive disorders.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

July 18, 2003

A handwritten signature in black ink that reads "Phyllis Spivack". The signature is written in a cursive, flowing style.

**PHYLLIS SPIVACK
PRIMARY EXAMINER**